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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/743,643	12/22/2003	Clifford Woolf	17633/2005	7171

29933 7590 07/05/2006

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EXAMINER	
MILLER, MARINA I	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 07/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/743,643	WOOLF ET AL.	
	Examiner	Art Unit	
	Marina Miller	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 December 2003*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-46* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-14, drawn to a composition comprising a plurality of polynucleotides, vectors, and host cells comprising the polynucleotides, classified in class 536, subclass 23.1.

II. Claims 15-18, drawn to a method of identifying an agent that increases or decreases expression of a polynucleotide sequence, classified in class 536, subclass 24.5.

III. Claims 19, drawn to a method for identifying a compound which regulates expression of a polynucleotide sequence, classified in class 435, subclass 5.

IV. Claims 20-22, drawn to a method for identifying a compound which increases or decreases pain, classified in class 435, subclass 69.1.

V. Claims 23-24, drawn to a method for producing a pharmaceutical formulation, classified in class 435, subclass 325.

VI. Claims 25-27, drawn to a method for identifying a compound which increases or decreases pain, classified in class 435, subclass 69.1.

VII. Claims 28-29, drawn to a method for identifying a compound which increases or decreases pain, classified in class 435, subclass 69.1

VIII. Claims 30-31, drawn to a method for identifying a compound useful in treatment of pain, classified in class 435, subclass 69.1.

IX. Claim 32, drawn to a method for producing a pharmaceutical formulation, classified in class 435, subclass 325.

X. Claim 33, drawn to a method of treating pain by administering an antisense polynucleotide, classified in class 514, subclass 44.

XI. Claim 34, drawn to a method of treating pain by administering a double stranded RNA molecule, classified in class 514, subclass 44.

XII. Claim 35, drawn to a method of treating pain by administering an antibody, classified in class 514, subclass 2.

XIII. Claim 36, drawn to a method of treating pain by administering a polypeptide, classified in class 514, subclass 2.

XIV. Claims 37-41, drawn to a method of detecting pain, classified in class 435, subclass 6.

XV. Claims 42-46, drawn to a method for detecting pain, classified in class 536, subclass 24.5.

The inventions are distinct, each from the other because of the following reasons:

The inventions are distinct, each from the other because of the following reasons: Invention I is drawn to a product. Inventions III-XVI are drawn to methods.

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the

product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the polynucleotides of Invention I may be used for other purposes, *e.g.*, as biological disease markers.

Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the polynucleotides of Invention I may be used for other purposes, *e.g.*, as biological disease markers.

Inventions I and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the method of Invention IV does not use the polynucleotide composition/array of Invention I, but only uses a polypeptide which is a separate and chemically distinct invention from the polynucleotide of Invention I.

Inventions I and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the method of Invention V does not use the polynucleotide of Invention I for producing a pharmaceutical formulation, but only uses a polypeptide which is a separate and chemically distinct invention from the polynucleotide of Invention I.

Inventions I and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the method of Invention VI does not use the polynucleotide of Invention I, but only uses a polypeptide which is a separate and chemically distinct invention from the polynucleotide of Invention I.

Inventions I and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the method of Invention VII does not use the polynucleotide of Invention I, but only uses a polypeptide which is a separate and chemically distinct invention from the polynucleotide of Invention I.

Inventions I and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the polynucleotides of Invention I may be used for other purposes, *e.g.*, as biological disease markers, which is different from the use as an identifier of a compound for the treatment of pain.

Inventions I and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the method of Invention IX does not use the polynucleotide of Invention I for producing a pharmaceutical formulation, but only uses a

polypeptide which is a separate and chemically distinct invention from the polynucleotide of Invention I.

Inventions I and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, polynucleoitdes of Invention I may be used for other purposes, *e.g.*, as biological disease markers, which is different from the use for the treatment of pain.

Inventions I and XI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, dsRNA in Invention XI which is identical, at least in part, to the polynucleotides of Invention I may be used for other purposes, *e.g.*, as biological disease markers, which is different from the use for the treatment of pain.

Inventions I and XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the method of treating pain by administering antibodies in Invention XII comprises using compounds which are separate and chemically distinct inventions from the polynucleotides of Invention I.

Inventions I and XIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation,

and effects (MPEP § 802.01 and § 806.06). In the instant case, the method of treating pain by administering polypeptides in Invention XIII comprises using compounds which are separate and chemically distinct inventions from the polynucleotides of Invention I.

Inventions I and XIV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the polynucleotides of Invention I may be used for other purposes, *e.g.*, as biological disease markers, which is different from the use as a detector of pain.

Inventions I and XV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the method of detecting pain by measuring polypeptides in Invention XV comprises using compounds which are separate and chemically distinct inventions from the polynucleotides of Invention I.

The inventions of Groups III-XVI are directed to various methods having various steps and purposes.

The methods of Groups II, III, VIII, XI, and XIV are distinct because they are physically and functionally different and are not required one for the other. The methods have different steps and goals. For example, a method of Invention II is directed to a method of identifying an agent that increases or decreases expression of a polynucleotide sequence comprising steps of administering an agent, hybridizing nucleic acids isolated from neurons to an array, and

measuring the hybridization. Invention XII is a method of treating pain by administering a double stranded RNA molecule wherein an mRNA transcript is obtained from a polynucleotide sequence. The same logic follows as to the differences between each distinct method wherein each method has different outcome and steps.

The methods of Groups IV-VII, IX, XII, XIII, and XV are distinct because they are physically and functionally different and are not required one for the other. The methods have different steps and goals. For example, a method of Invention V is drawn to a method for identifying a compound which increases or decreases pain comprising steps of providing a cell comprising a polypeptide, contacting the cell with a compound, and measuring the activity of a polypeptide. Invention XII is directed to a method of treating pain by administering an antibody which binds to a polypeptide. The same logic follows as to the differences between each distinct method wherein each method has different outcome and steps.

The methods of Groups II, III, VIII, XI, and XIV and the method of Groups IV-VII, IX, XII, XIII, and XV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). All methods involve different method steps and are directed to separate and distinct outcome. Also, the methods of Groups II, III, VIII, XI, and XIV use polynucleotides and the method of Groups IV-VII, IX, XII, XIII, and XV use polypeptides, that makes them distinguishable inventions each from the other.

Because these Inventions are distinct for the reasons given above, the classification is different, and the non-patent and patent literature search required for each group is not

coextensive with that requirement for another group, restriction for examination purposes as indicated is proper.

Sequence Election

In addition, each Group detailed above reads on patentably distinct sequences. Absent evidence to the contrary, each sequence is presumed to represent an independent and distinct invention, subject to restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq.

For an elected Group drawn to nucleotide sequences, applicants must further elect a single polynucleotide sequence. (*See* MPEP § 803.04). For an elected Group drawn to amino acid sequences, applicants must further elect a single amino acid sequence. Each sequence is patentably distinct because they are unrelated sequences and have different structure and function.

It has been determined that 1 (ONE) sequence constitutes a reasonable number for examination purposes under the present conditions. At present, the huge number of submissions of claims directed to various sequences, such as nucleic acids or polypeptides, is so large that the election of 1 (one) sequence of this type is now deemed to be practically appropriate so as to not overwhelm the examination and search process for such claims.

It is recognized that the claims of at least Group I are directed to a combination or plurality of nucleotides. The requirement for election of a single sequence set forth above is considered an election of species for purposes of search and a starting point for examination. Applicant is assured that if the elected sequence is found to be free of the prior art, the search will be expanded to other species encompassed by the claims.

Species Election

The application contains claims directed to the following patentably distinct species of the claimed invention:

Species A: elect one candidate compound; *e.g.*, from those recited in claims 21-22 and 26-27.

Species B: elect one small molecule component; *e.g.*, from those recited in claim 29.

Species of group A, different compounds, are distinct because they have different structure and function and are unrelated.

Species of group B, different small molecules, are distinct because they have different structure and function and are unrelated.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species from group A recited above, where applicable, for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the

limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marina Miller whose telephone number is (571)272-6101. The examiner can normally be reached on 8-5, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, Ph. D. can be reached on (571)272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would

like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Marina Miller
Examiner
Art Unit 1631

MM

MARJORIE A. MORAN
PRIMARY EXAMINER
6/22/04